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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,136	01/27/2004	Walter J. Leclair	WLD-002	1966

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LAHIVE & COCKFIELD  
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BOSTON, MA 02109

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/766,136	<b>Applicant(s)</b> LECLAIR, WALTER J.	
	<b>Examiner</b> Mary Hoffman	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Interview Summary***

To further clarify the record as requested by applicant in the response filed 6/29/2006, please note that lines 17-18 of the Interview Summary dated 6/19/2006 should read, "Because applicant's representative did not provide a formal response with the exact claim language that he intends to add, the examiner was unable to definitively indicate whether or not the proposed amendment would overcome the previous rejection." It is noted that the purpose of the interview was to discuss proposed amendments to the claims, and the examiner made it clear that she would neither definitively indicate whether or not the proposed amendments overcame the cited art nor make any statements regarding the allowability of the claims until after the submission of the formal response and review with her Supervisory Patent Examiner. Therefore, since the examiner made no definitive statements during the telephonic interview and further stated that Applicant's arguments would be further considered upon the filing of a formal response, it is the examiner's opinion that the Interview Summary clearly reflects the record.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 9-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dudasik (WO 02/34120).

Dudasik discloses a bone fastener having a shaft having a first end and a second end (FIG. 7a-7c+). A screw thread extending from the second end circumnavigates the shaft (page 6, 2<sup>nd</sup> paragraph). A plurality of elongate slots is formed longitudinally in the shaft from the second end, creating a plurality of furcated branches. The plurality of branches bend radially outwardly from a first screw diameter to a relatively larger second circumferential diameter. The plurality of furcated branches can compress to the first screw diameter state when the fastener is initially positioned at the opening of a hole. The plurality of furcated branches return to the second circumferential diameter upon reduction of a radially compressive force. The plurality of furcated branches extends for a distance of at least half of the length of the shaft. The screw thread extends from the second end of the shaft at least substantially to the first end of the shaft. A screw head is disposed at the first end of the shaft. The fastener comprises a driver recess disposed at the first end of the shaft (see hole in screw head). The plurality of furcated branches has sufficient flexibility. The fastener is formed from titanium.

Claims 1-7 and 9-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Drewry et al. (U.S. Patent No. 6,436,099).

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Drewry et al. disclose a bone fastener having a shaft having a first end and a second end (FIG. 9E). A screw thread extending from the second end circumnavigates the shaft (ref. #52). A plurality of elongate slots is formed longitudinally in the shaft from the second end, creating a plurality of furcated branches. The plurality of branches bend outwardly from a first screw diameter to a relatively larger second circumferential diameter. The plurality of furcated branches can compress to the first screw diameter state when the fastener is initially positioned at the opening of a hole. The plurality of furcated branches return to the second circumferential diameter upon reduction of a radially compressive force. The plurality of furcated branches extends for a distance of at least half of the length of the shaft. The screw thread extends from the second end of the shaft at least substantially to the first end of the shaft. A screw head is disposed at the first end of the shaft. The fastener comprises a driver recess disposed at the first end of the shaft (see hole in screw head). The plurality of furcated branches has sufficient flexibility. The fastener is formed from titanium.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the Dudasik and Drewry et al. references, which are capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is

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intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dudasik (WO 02/34120).

Dudasik disclose the claimed invention except for the plurality of furcated branches comprises three branches.

With regard to claim 8, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the plurality of furcated branches of Dudasik comprising three branches, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drewry et al. (U.S. Patent No. 6,436,099).

With regard to claim 8, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the plurality of furcated branches

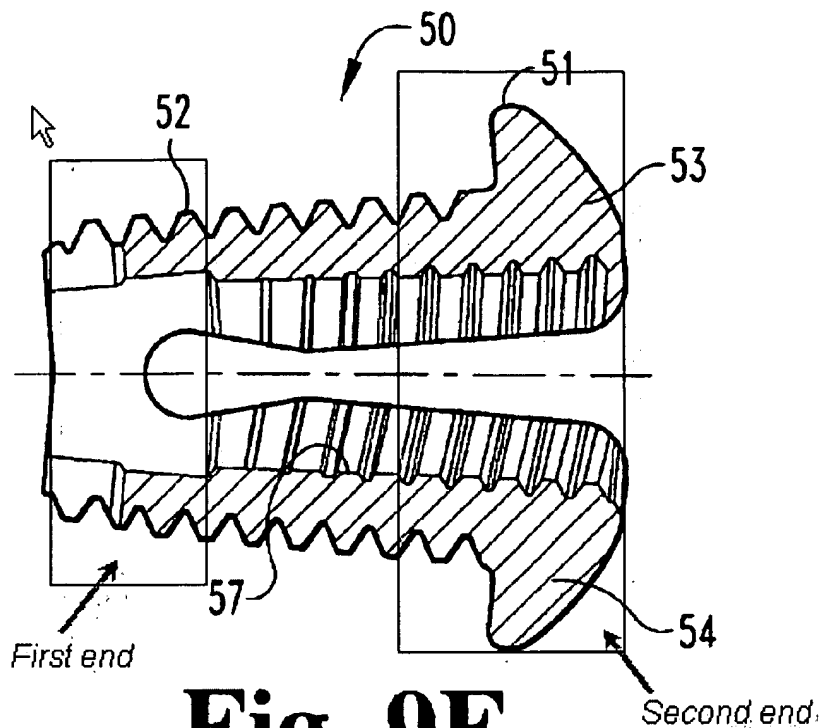
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of Drewry et al. comprising three branches, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

In response to Applicant's argument that the Dudasik reference does not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., permitting the existence of both conditions at the same time (bending radially outwardly and being compressible to the first screw diameter simultaneously) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. Therefore, for claims 1 and 11, it is the examiner's opinion that the Dudasik reference does disclose that both the plurality of branches bend radially outwardly as well as the plurality of branches are compressible to the first screw diameter without plastic deformation.

Applicant's arguments that the Drewry reference does not disclose "a screw thread extending from the second end...slots longitudinally formed in the shaft from the second end and creating a plurality of furcated branches", the examiner disagrees. After consultation with S.P.E. Examiner Robert, it was determined that the limitation "extending from the second end" is not specific enough to distinguish the invention of the application from the Drewry et al. reference. See the marked-up figure (next page) to illustrate this point.



Drewry et al. (U.S. Patent No. 6,436,099)

A suggestion to aid in overcoming the Drewry et al. reference is to specify that there is an enlarged screw head is at the first end and the slots are located at the second end.

In response to applicant's argument that the devices of Drewry et al. and Dudasik are used for a different purpose, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.



Applicant's arguments with regard to claim 8 do not overcome the rejections applied thereto, since applicant has not provided any convincing showing that these are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al. On page 5, lines 9-13, applicant states the there can be any number of branches, therefore, the limitation of claim 8, "the plurality of furcated branches comprising three branches", is not critical.

In response to Applicant's remarks concerning the Enyati reference, please note that this typo has been corrected in the above rejection, which now states, "With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the Dudasik and Drewry et al. references, which are capable of being used as claimed if one so desires to do so." It is furthermore acknowledged that the claim rejections under Enyati were previously withdrawn in response to Applicant's arguments in the response filed 2/13/2006.

The rejections are therefore deemed final.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

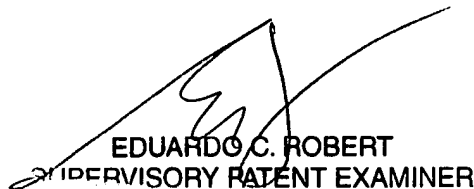
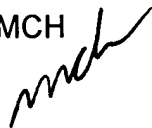
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER